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14. ABSTRACT

Purpose: To examine whether the use of an auricular acupuncture (AA) regimen improves sleep quality for veterans with post-traumatic stress disorder (PTSD). **Design**: A prospective, randomized, wait-list controlled feasibility study. Aim#1: Compare AA acceptability between veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone. Aim #2: Compare sleep quality at baseline and at five weeks in veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone. Aim #3: Compare PTSD and depressive symptoms at baseline and at week five in veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone. Aim#4: Compare PTSD and depressive symptoms at baseline, week three, and week five between veterans who receive AA or receive standard PTSD therapy alone. **Methods**: Subjects were randomized to receive AA with PTSD treatment or PTSD treatment alone. Acceptability was evaluated using a likert scale, feasibility with a consort diagram. Sleep quality was evaluated with the Pittsburgh Sleep Quality Index (PSQI), and actigraphy. **Sample**: Active duty veterans with PTSD in a residential PTSD treatment program. **Analysis**: Acupuncture acceptability between groups was analyzed utilizing a Likert 1-5 scale. RMANOVA was conducted to analyze PSQI scores and actigraphy data. **Findings**: There were n = 12/15 in the AA group and n = 8/14 in the control group. Attrition rates were higher in the control group (43% vs. 20%, P = 0.24). The AA group reported AA was a more acceptable treatment for sleep disturbance than subjects in the control group (AA median = 5 vs. control median = 3, P = 0.004). Significant differences between groups were found on sleep quality and daytime dysfunction components of the PSQI (p = 0.003, P = 0.004). **Implications for Military Nursing**: Military nurses can practice AA, which has expanded non-pharmacologic sleep treatments available to veterans with PTSD.

15. SUBJECT TERMS					
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Acupuncture for Disturbed Sleep in Veterans with Post Traumatic Stress Disorder

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Table of Contents

Abstract

Purpose: To examine whether the use of an auricular acupuncture (AA) regimen improves sleep quality for veterans with post traumatic stress disorder (PTSD).

Design: A prospective, randomized, wait-list controlled feasibility study.

Aim#1: Compare AA acceptability between veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone.

Aim #2: Compare sleep quality at baseline and at five weeks in veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone.

Aim #3: Compare PTSD and depressive symptoms at baseline and at week five in veterans who receive AA with standard PTSD therapy or standard PTSD therapy alone.

Aim#4: Compare PTSD and depressive symptoms at baseline, week three, and week five between veterans who receive AA or receive standard PTSD therapy alone.

Methods: Subjects were randomized to receive AA with PTSD treatment or PTSD treatment alone. Acceptability was evaluated using a likert scale, feasibility with a consort diagram. Sleep quality was evaluated with the Pittsburgh Sleep Quality Index (PSQI), and actigraphy.

Sample: Active duty veterans with PTSD in a residential PTSD treatment program.

Analysis: Acupuncture acceptability between groups was analyzed utilizing a Likert 1-5 scale. RMANOVA was conducted to analyze PSQI scores and actigraphy data.

Findings: There were n = 12/15 in the AA group and n = 8/14 in the control group. Attrition rates were higher in the control group (43% vs. 20%, P = 0.24). The AA group reported AA was a more acceptable treatment for sleep disturbance than subjects in the control group (AA median = 5 vs. control median = 3, P = 0.004). Significant differences between groups were found on sleep quality and daytime dysfunction components of the PSQI (p = 0.003, P = 0.004).

Implications for Military Nursing: Military nurses can practice AA, which has expanded non-pharmacologic sleep treatments available to veterans with PTSD.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☒ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Summary of Significant Events

Type of Event	Grant Agreement Number HT9404-12-1-TS15	Date of IRB or IACUC Approval (if applicable)
Adverse Events: 6/9/13: Subject #7, fall, PI notified 6/14/13, Research Monitor notified 6/14/13. AE deemed unrelated to study. 6/7/13: Subject #9, became intoxicated, PI notified 6/14/13, Research Monitor notified 6/14/13. AE deemed unrelated to study. 6/7/13: Subject #10, sprained wrist, PI notified 6/14/13, Research Monitor notified 6/14/13. AE deemed unrelated to study. 7/5/13: Subject #14, became intoxicated, PI notified 7/22/13, Research Monitor notified 7/22/13. AE deemed unrelated to study. 7/5/13: Subject #29, suicidal ideation, PI notified 7/22/13, Research Monitor notified 7/22/13. AE deemed unrelated to study.		6/24/13 Approved by NMCSD IRB for AEs dated 6/9/13 & 6/7/13 7/23/13 Approved by NMCSD IRB 10/12/13 Approved by NMCSD IRB

Progress Towards Achievement of Specific Aims of the Study or Project

Research Purpose

The purpose of this research was to conduct a small-scale feasibility study to examine whether the use of an auricular acupuncture (AA) regimen improves sleep quality for OEF/OIF veterans with PTSD and self-reported sleep disturbance. This proposal sought to answer the following general research question: "What effect does AA have on sleep quality among OEF/OIF veterans with PTSD and self-reported sleep disturbances?"

Research Question #1: Is the use of an AA regimen for veterans with PTSD and self- reported sleep disturbance acceptable and feasible?

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an AA intervention study utilizing a consort diagram to track subject disposition throughout the study period.

Hypothesis #1: Subjects who receive AA will view it as a more acceptable treatment for sleep disturbance than those who receive standard therapy alone.

Progress toward Aim#1: Acupuncture acceptability between groups was analyzed by examining responses to a 1-5 likert type question (Table 1). A Mann Whitney U test was used to analyze likert scores between groups. Subjects in the AA intervention group viewed the AA as a more acceptable treatment for sleep disturbance (*Mdn* = 5) than subjects in the control group (*Mdn* = 3) $U = 12.0$, $z = -2.99$, $p = .004$). The majority of subjects in the control group selected the response: "undecided if acupuncture is an acceptable treatment for sleep disturbance." The majority of subjects in the control group had never experienced acupuncture treatments, and were therefore undecided about its effects.

Table 1. Acupuncture Acceptability Between Groups

Likert Question: "Please circle the number below which most closely describes your view of acupuncture as an acceptable treatment for sleep"	AA Group (*n* = 12)	Control Group (*n* = 8)
	n, %	*n*, %
1. Completely disagree that acupuncture is an acceptable treatment for sleep disturbance.	0 (0)	0 (0)
2. Disagree that acupuncture is an acceptable treatment for sleep disturbance.	0 (0)	0 (0)
3. Undecided if acupuncture is an acceptable treatment for sleep disturbance.	1 (8)	7 (87.5)
4. Agree that acupuncture is an acceptable treatment for sleep disturbance.	4 (33)	0 (0)
5. Completely agree that acupuncture is an acceptable treatment for sleep disturbance.	7 (58)	1 (12.5)

Feasibility of conducting this study was evaluated by examining a consort diagram (figure 1). Study recruiting briefs were presented every ten weeks as each new cohort arrived at the residential PTSD treatment program. Thirty subjects were recruited over an eight-month period. Subject recruitment was slower than expected due to another study recruiting at the same site. Of the 30 subjects, which enrolled in the study, 10 subjects did not complete the study. This

resulted in an overall attrition rate of 33% (attrition rate in the AA intervention group was 20% while attrition rate in the control group was 43%). The high attrition rate experienced in this study was largely attributed to subjects withdrawing from the residential treatment program and subsequently from the study (n = 7). One subject was disenrolled from the study due to scoring high on the STOP Bang Questionnaire (OSA screening instrument). This subject's primary care provider was informed of the score on the STOP Bang and he was scheduled for a sleep study. Two subjects voluntarily withdrew from the study. Both subjects, who voluntarily withdrew from the study, were randomized to the treatment group. One subject stated he was overwhelmed with the requirements of the study in addition to the PTSD treatment program. The second subject withdrew after he received one treatment and described feeling uncomfortable during the AA treatment.

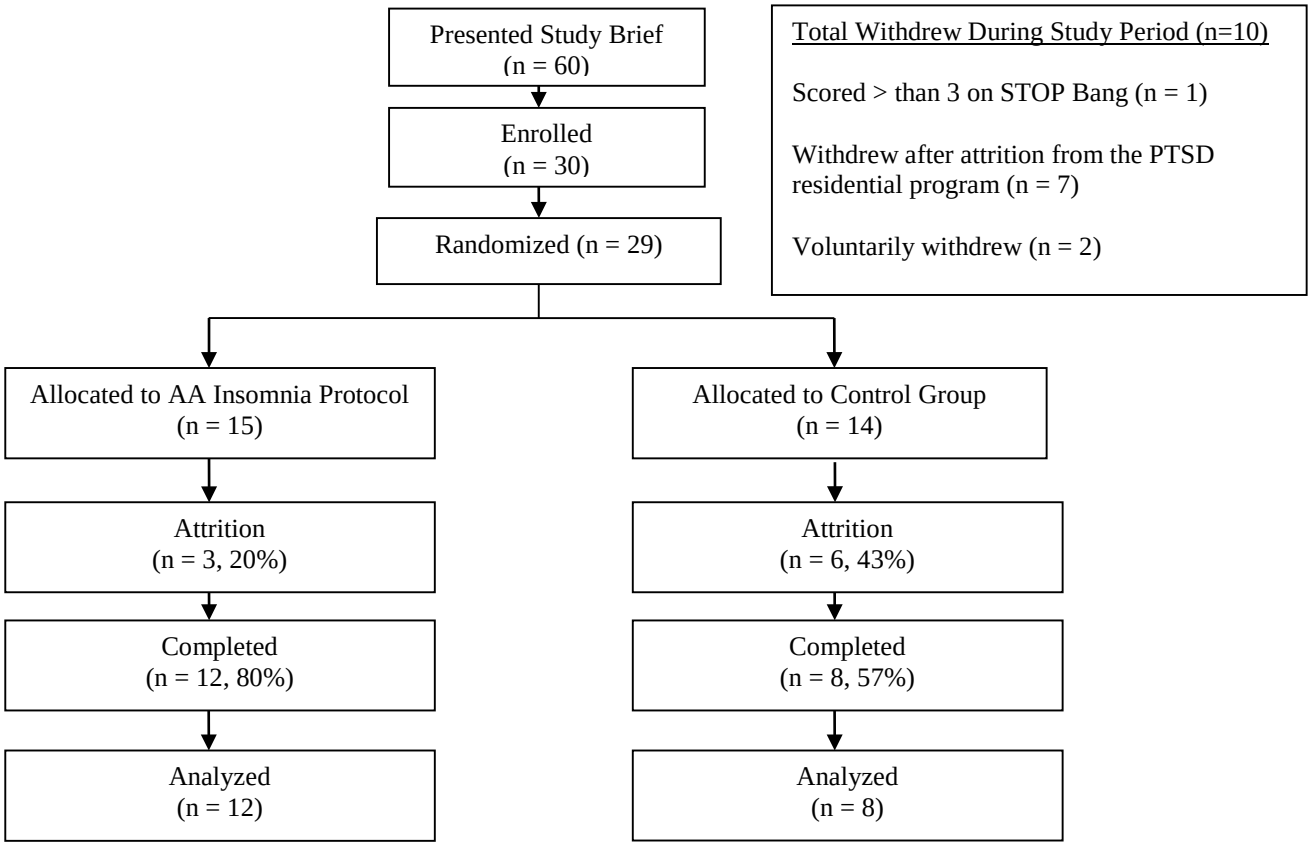


Figure 1. Consort Diagram

Additionally, feasibility of this study was evaluated by examining subject participation in the AA treatments and adherence of subjects wearing the actigraphs and recording sleep times in the sleep diary (Table 2).

Overall, subjects in the AA group readily participated and engaged in the AA treatments. The mean number of completed treatments in the intervention group was 8.42 (SD ± .996) while the mean number of completed treatments in the control group was 8.4 (SD ± .99). Reasons for missed treatments included forgetting treatments and schedule conflicts. Missed treatments were

documented, and subjects were rescheduled for additional AA treatments within the three-week intervention period as described in the study protocol.

Subjects were asked to wear actigraphs for a total of 14 nights. The mean number of scorable actigraphy nights for all subjects in the sample was 9.9 (SD ± 3.5). Subjects in the intervention group had a mean of 9.33 ± 4.2 scorable actigraphy nights, in comparison to subjects in the control group who had a mean of 10.75 ± 2.3 scorable actigraphy nights (p = .689).

Similarly, subjects were asked to record sleep information for a total of 14 nights. Subjects in the intervention group recorded sleep diary information fewer nights (μ = 10.75 ± 3.5) when compared to subjects in the control group (μ = 13.5 ± .76; p = 0.083).

Although the use of actigraphy and sleep diary instruments were feasible in this study, some challenges with subject compliance were experienced. Several subjects described taking the actigraphy watch off to shower and forgetting to replace the actigraph on their wrist. Several subjects also described memory deficits, and therefore missed several nights of recording sleep times in the sleep diary. Compliance with both the actigraphy and sleep diary was better in the control group. This was speculated to be a result of the intervention group immediately receiving the AA intervention, whereas the control group had to wait to receive the AA treatment. The control group may have perceived that if the study instruments were not completed then they would not receive the AA treatment. The use of incentives in this population may improve compliance with both actigraphy and sleep diary data.

Table 2. Adherence Data

Adherence Data	AA (n = 12) μ, SD	Control (n = 8) μ, SD
Scorable Nights of Actigraphy	9.3 ± 4.2	10.8 ± 2.3
Scorable Nights of Sleep Diary	10.8 ± 3.4	12.6 ± 2.8
Number of Treatments Received	8.4 ± .996	6.5 ± 3.9
Note: A total of 14 nights of actigraphy and sleep diary data were possible & a total of 9 treatments were offered to subjects.		

Subject acceptability was examined by responses to an open-ended question: "Please write any comments or feedback in the space below regarding your participation in this study, and any recommendations for future studies with acupuncture."

The original intent of this question was to obtain information from subjects to develop future study protocols using AA treatments. The comments subjects wrote in response to this question described a wide variety of benefits of receiving AA treatments. The quotations below are from two subjects and are representative of the comments made by subjects participating in this study.

Subject # 19"My sleep significantly improved due to acupuncture. I felt better rested and helped me concentrate on my days and I performed better on my daily activities. I would definitely recommend this type of treatment for sleep."

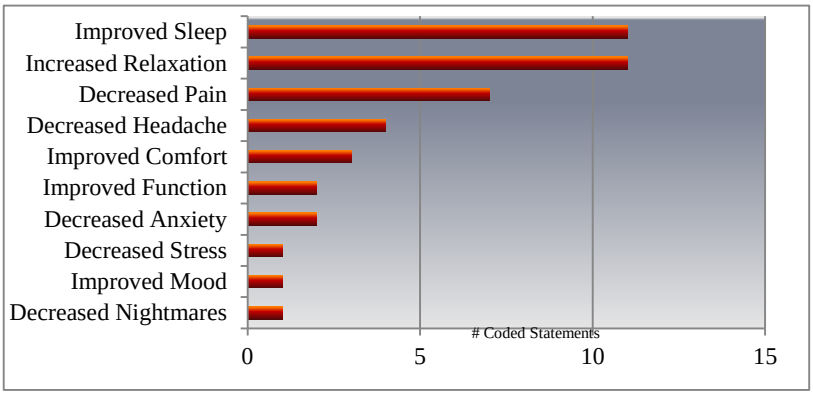
Subject #28"I have been dealing with pain for the past 7 years and for the first [time] without the aid of narcotics I have been able to relax and sleep. I was able to actually get full rest and had energy throughout the day. Acupuncture at the end of the day helped with all the trauma that we relive in therapy. It was such a great thing to look forward to."

An amendment was submitted to the NMCSD IRB, USD IRB and to TSNRP to analyze the open-ended comments of participants in this study. The amendment was approved by Naval Medical Center San Diego Investigational Review Board, the University of San Diego Investigational Review Board, and TSNRP.

The qualitative data was analyzed using a thematic content analysis approach. The purpose of the analysis was to gain a better understanding of the perceived benefits of receiving an AA insomnia regimen. Data was transcribed and reviewed for accuracy. Two investigators on the study thematically coded the transcripts independently. Coding was reviewed, and themes that emerged were discussed to ensure that they were grounded in the transcripts. Validation and consensus on themes were reached by referring back to the original transcripts.

Three predominant themes emerged from the data: (1) improved sleep, (2) increased relaxation, and (3) decreased pain (Table 3). A manuscript to disseminate the qualitative results is currently under development.

Table 3. Qualitative Data



n = 20, *16 subjects responded, 4 subjects no response

Research Question #2: Is there a difference in objective and subjective sleep disturbances and sleep quality at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI and sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #2: Objective and subjective sleep disturbances and sleep quality will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Progress towards Aim #2:

1) Objective sleep measures: Sleep onset latency (SOL), wake after sleep onset (WASO), sleep efficiency (SE), number of awakenings (NOA), and total sleep time (TST) were measured by actigraphy. Baseline actigraphy measures were not significantly different between groups with the exception of number of awakenings (NOA), which was lower in the control group (Table 4). However, at week five, no significant differences were noted for NOA between

groups. Further, no significant differences were found in actigraphy sleep measures between the AA ($p > .05$) or control group ($p > .05$) at week five (Table 5). Both groups demonstrated increased SOL, WASO, and NOA at week five and decreased SE and TST. Although these changes indicate a worsening of sleep measures, these changes are consistent with patients undergoing intensive cognitive processing therapy and the changes in sleep measures were similar between groups.

Table 4. Baseline Actigraphy Measures

Baseline Actigraphy Measures	AA Group (n = 12)	Control (n =8)	p Value
	μ, SD	μ, SD	
SOL	47.6 (±30.0)	40.2 (±26.3)	.734
WASO	34.4 (14.3)	22.9 (13.3)	.070
SE	92.4 (±3.2)	94.3 (±3.0)	.180
NOA	15.6 (±4.4)	11 (±4.2)	.044*
TST	462 (±49.0)	413.3(±77.5)	.107

Note. SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; NOA = number of awakenings; TST = total sleep time. Results presented as μ ± SD. Independent student's t test. Mean difference is the mean change in score within each group from Week 1 to Week 5. Missing actigraphy data for two subjects in the intervention group.

Table 5. Week Five Actigraphy Measures

Week Five Actigraphy Measures	AA Group μ, SD	Mean Difference	Control Group μ, SD	Mean Difference	p Value
SOL	58.4± 43.9	10.8	65.9 ± 40.5	25.7	.50
WASO	41.1 ± 15.1	6.7	49.8 ± 43.5	26.9	.24
SE	90 ± 4.3	-2.4	88.5 ± 9.1	-5.8	.36
NOA	16.5 ± 5.6	0.9	16.6 ± 6.6	5.6	.14
TST	417 ± 68.2	-44.4	394.5 ± 82.5	-18.8	.81

Note. SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; NOA = number of awakenings; TST = total sleep time. Results presented as μ ± SD. 2 x 2 Repeated Measures ANOVA. Mean difference is the mean change in score within each group from Week 1 to Week 5. Missing actigraphy data for two subjects in the intervention group.

2) Subjective sleep measures: SOL, WASO, SE, NOA, and TST were also measured by sleep diary. Baseline sleep diary measures were not significantly different between groups (Table 6). Further, no significant differences were found in sleep diary measures between the AA ($p > .05$) or control group ($p > .05$) at week five (Table 7). Both groups demonstrated increased WASO and SE and decreased NOA and TST. However, unlike the actigraphy sleep measures, SOL decreased in the AA intervention group and increased in the control group, but this difference was not statistically significant. Similar to the actigraphy results, these changes indicate a worsening of sleep measures and are consistent with patients undergoing intensive cognitive processing therapy.

Sleep diary measures recorded by subjects overestimated SOL, WASO, SE, and TST when compared with actigraphy measures. These findings are consistent with previous studies in which subjects with insomnia overestimate time spent awake at night and underestimate sleep time at night.[1] One exception in this study was NOA, which was lower in the sleep diary measures than actigraphy measures. However, subjects with PTSD frequently report restless sleep and this may have affected NOA recorded by actigraphy.

Table 6. Baseline Sleep Diary

Baseline Sleep Diary Values	AA Group (n = 12)	Control (n =8)	p Value
	μ, SD	μ, SD	
SOL	68.2 (±47.5)	88.8 (±37.3)	.210
WASO	55.6 (±46.2)	49.7 (±51.1)	.724
SE	58.5 (±15.3)	62.2 (±17.5)	.793
NOA	3.2 (±.88)	2.7 (±1.8)	.896
TST	344.5 (±118.3)	325.7(±113.4)	.427

Note. SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; NOA = number of awakenings; TST = total sleep time. Results presented as μ ± SD. Means represent group means in minutes. Independent student's t test.

Table 7. Week 5 Sleep Diary

Week Five Sleep Diary Measures	AA Group μ, SD	Mean Difference	Control Group μ, SD	Mean Difference	p Value
SOL[a]	36 ± 26.6	-32.2	89.3 ± 134	0.5	.56
WASO[b]	72.7 ± 80.5	17.1	85.9 ± 166.2	36.2	.82
SE[b]	73.3 ± 16.7	14.8	70.7 ± 30.4	8.5	.65
NOA[c]	2.1 ± 1.2	-1.1	2.1 ± 1.8	-0.6	.66
TST[d]	74.3 ± 15.5	-270.2	73.6 ± 28.8	-252.1	.76

Note. SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; NOA = number of awakenings; TST = total sleep time. Results presented as μ ± SD. Means represent group means in minutes. 2 x 2 Repeated Measures ANOVA. Mean difference = change in-group mean from baseline to week five. [a]missing sleep diary data for seven subjects in the intervention group and two subjects in the control group, [b]missing sleep diary data for six subjects in the intervention group and two subjects in the control group, [c]missing data from seven subjects in the intervention group and one subject in the control group, [d]missing sleep diary data for five subjects in the intervention group and one subject in the control group.

Subjective sleep measures continued: Baseline PSQI scores were not significantly different between groups with the exception of the sleep duration component. This component was higher in the control group (Table 8); however at week five there were no significant differences for sleep duration component scores between groups (Table 9).

At week five, differences in overall sleep quality as measured by the PSQI were also not significant between groups ($F_{1,18}$ = 10.4, p = .082) (Table 9 and Figure 2). However, at week five, two of the PSQI component scores were statistically significant between the AA intervention group and control group (daytime dysfunction and overall sleep quality). A significant group by time interaction was found for daytime dysfunction ($F_{1,18}$ = 10.8, p = .004, η^2 = .375). Analysis of simple effects found there was an increase in daytime dysfunction mean scores for the control group (p = .197). While the intervention group showed a significant decrease in daytime dysfunction mean scores (p = .005). Daytime dysfunction scores were significantly lower after the treatment in the intervention group (p = .023) (Table 9 and Figure 3).

A significant group by time interaction for the sleep quality component was found between groups ($F_{1,18}$ = 11.4, p = .003) (Table 9 and Figure 4). Analysis of simple effects found there was a decrease in the sleep quality mean scores for the intervention group (p = .001), while there was no change in mean scores for the control group (p = 1.00). There were no differences between the groups at baseline. Sleep quality scores were lower after the treatment in the intervention group (p = .057) and were approaching statistical significance.

Table 8. Baseline PSQI Scores

Baseline PSQI Scores	AA Group (n = 12)	Control (n =8)	p Value
	μ, SD	μ, SD	
Global PSQI	17.3 ± 2.7	17.5 ± 1.6	.87
Sleep Quality	2.5 ± 0.52	2.38 ± 0.52	.61
Sleep Latency	2.92 ± 0.29	3.0 ± .00	.42
Sleep Duration	2.3 ± 0.78	3.0 ± .00	.01*
Sleep Efficiency	2.33 ± 1.2	2.6 ± 1.1	.59
Sleep Disturbance	2.4 ± 0.52	2.0 ± 0.93	.21
Sleep Medications	2.5 ± 0.93	2.5 ± 0.65	.99
Daytime Dysfunction	2.3 ± 0.65	2.0 ± 0.76	.31
Note. PSQI (range 0-21), component scores (range 0-3), higher scores indicate decreased sleep quality. Results presented as μ ± SD. Independent student's t test.			

Table 9. Week Five PSQI Scores

Week Five PSQI Scores	AA Group μ, SD	Mean Difference	Control Group μ, SD	Mean Difference	p Value
PSQI Global	14 ± 3.4	-3.3	16.3 ± 2.8	-1.25	.08
Sleep Quality	1.8 ± .75	-0.7	2.4 ± .52	.02	.003*
Sleep Latency	2.2 ± .84	-0.7	2.6 ± .52	-0.4	.29
Sleep Duration	1.4 ± .80	-0.9	2.3 ± .70	-0.7	.23
Sleep Efficiency	1.9 ± .90	-0.4	2.0 ± 1.2	-0.6	.75
Sleep Disturbances	2.1 ± .67	-0.3	2.0 ± .93	0	.31
Sleep Medication	3.0 ± .00	0.5	2.6 ± 1.1	0.1	.52
Daytime Dysfunction	1.6 ± .67	-0.7	2.3 ± .74	0.3	.004*
Note. Results presented as μ ± SD. Mean difference is the mean change in score within each group from Week 1 to Week 5. n = 20, 2 x 2 Repeated Measures ANOVA was performed on the PSQI global score and component scores. Component scores further analyzed with simple effects test to confirm findings.					

Figure 2. PSQI Overall Sleep Quality Scores

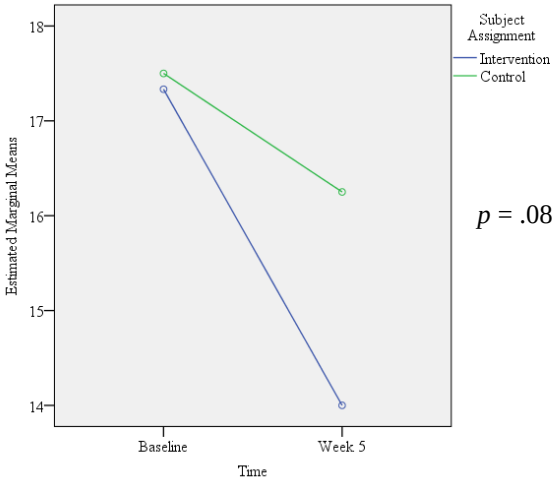
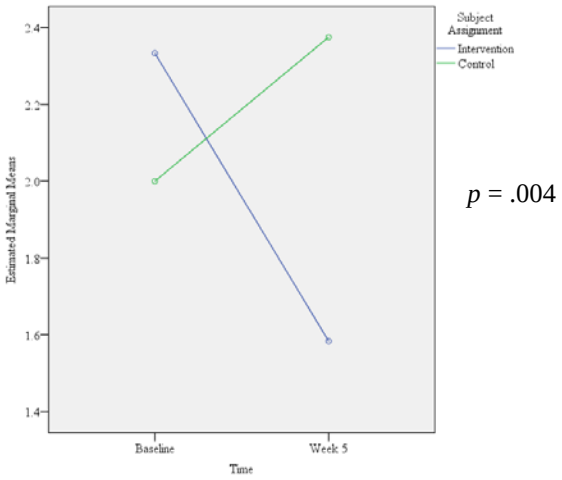
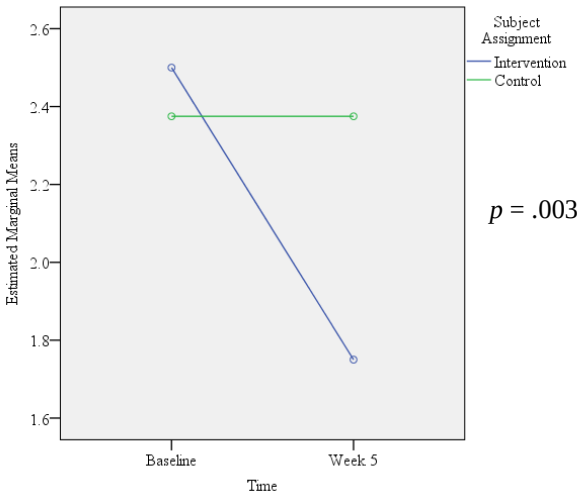


Figure 3. PSQI Daytime Dysfunction Component Interaction by Group Assignment



$p = .004$

Figure 4. PSQI Sleep Quality Component Interaction by Group Assignment



$p = .003$

Research Question #3: Is there a difference in PTSD symptoms and depressive symptoms at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture or standard PTSD therapy?

Aim #3: Compare PTSD symptoms and depressive symptoms at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Hypothesis #3: PTSD symptoms and depressive symptoms will be improved in OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

Progress towards Aim #3: PTSD symptoms as measured by the PCL and depression symptoms as measured by the PHQ were not significantly different at baseline or at five weeks between

groups (p >.05) (Table 10 and Table 11). PCL and PHQ scores at week five were analyzed by the Repeated Measures ANOVA test.

Table 10. PCL and PHQ Scores at Baseline

Baseline PCL and PHQ Scores	AA Group (n = 12)	Control (n =8)	p Value
	μ, SD	μ, SD	
PCL	68.5 ± 11.9	70.6 ± 7.5	.66
PHQ	18.4 ± 4.9	19.0 ± 4.2	.79
Note. Post Traumatic Stress Disorder Checklist Military Version (PCL) (range 17-85), with scores > 50 indicating a high likelihood of PTSD. Patient Health Questionnaire (PHQ) (range 0-27) severity of depression: 0-4 minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression. Results presented as μ ± SD. Independent student's t test.			

Table 11. PCL and PHQ Scores at Five Weeks

Baseline PCL and PHQ Scores	AA Group (n = 12)	Control (n =8)	p Value
	μ, SD	μ, SD	
PCL	68.9 ± 12.0	72 ± 5.9	p = .85
PHQ	16.6 ± 4.9	15.4 ±3 4.9	p = .28
Note. Post Traumatic Stress Disorder Checklist Military Version (PCL) (range 17-85), with scores > 50 indicating a high likelihood of PTSD. Patient Health Questionnaire (PHQ) (range 0-27) severity of depression: 0-4 minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, 20-27 severe depression. Results presented as μ ± SD. Repeated measures analysis of variance.			

Research Question #4: Is there a difference in PTSD symptoms and depressive symptoms during the study period between OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy?

Aim#4: Compare PSTD symptoms (PCL-M) and depressive symptoms (PHQ) weekly during the study period (baseline, week one, two, three, four, five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

Hypothesis #4: PTSD symptoms and depressive symptoms will be improved during the study period among OEF/OIF veterans with PTSD who receive auricular acupuncture as compared to those that receive standard PTSD therapy.

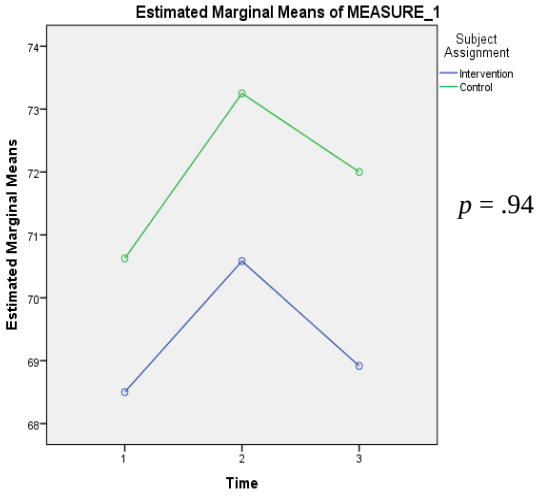
Progress towards Aim #4: A modification for this aim was requested and approved by the Naval Medical Center San Diego IRB, University of San Diego IRB, and TSNRP. This modification was requested because the clinic where this study was performed changed the administration of the PCL and PHQ from every week to every two weeks. Aim #4 was changed to the following:

Aim#4: Compare PSTD symptoms (PCL-M) and depressive symptoms (PHQ) every two weeks during the study period (baseline, week three, and week five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

PTSD symptoms as measured by the PCL and depression symptoms as measured by the PHQ were not significantly different at baseline, week three, or at five weeks between groups p >.05

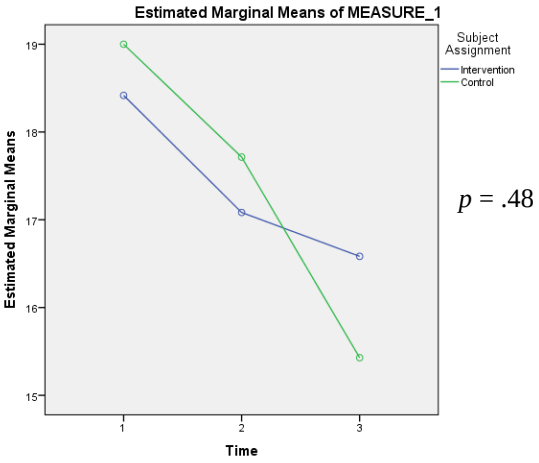
(Figure 5 and Figure 6). PCL and PHQ scores were analyzed by a Repeated Measures ANOVA test.

Figure 5. PCL at Baseline, Week 3, and Week 5



$p = .94$

Figure 6. PHQ at Baseline, Week 3, and Week 5



$p = .48$

Relationship of current findings to previous findings:

The current study has provided some preliminary evidence that AA treatments are acceptable to veterans with PTSD and may improve subjective sleep quality among veterans with PTSD and sleep disturbances. Prior to this study, several studies had reported improvements in sleep quality among patients with insomnia who received AA treatments,[2,3] however, the investigators were unable to identify any previous studies that examined the use of AA for the use of insomnia among veterans with PTSD. During the data collection period of the current study (USU Grant Number HT9404-12-1-TS15, USU Project Number N12-P15); two investigations examining the use of AA for PTSD related insomnia among veterans were published. Prisco et al. examined the use of an AA protocol with five acupoints administered in a

group setting twice weekly for an eight week period to veterans with PTSD and insomnia.[4] Subjects in this study were randomized to one of three groups: 1) a true AA group, 2) an AA sham group, or 3) a wait-list control group. Outcome measures for this study were subjective sleep quality (measured by Insomnia Severity Index and Morin Sleep Diary) and objective sleep measures (TST, SOL, SE, and total nap time measured by actigraphy).

Statistically significant differences in sleep quality as measured by the ISI for subjects in the true AA group as compared to the sham AA group or the wait list control group were reported at one month ($p = .0165$).[4] No statistically significant differences for sleep measures by actigraphy between groups were found. The results of this study are promising; however, this study was limited by several factors. Limitations of this study include: 1) small sample size (n = 25, true AA group = 8, sham AA group = 8, wait list control group = 9), 2) the use of music during the AA intervention, and 3) conventional care received by subjects during the study period were not monitored.

A second investigation examining the use of AA for PTSD related insomnia among veterans was also published. Cronin at al. examined the use of the National Acupuncture Detoxification Association (NADA) protocol administered the NADA protocol daily for five consecutive days to veterans with previous combat exposure.[5] Subjects in this study were randomly assigned to either an intervention group or a wait list control group. Outcome measures were subjective sleep quality as measured by the PSQI and PTSD symptoms as measured by the PTSD Military Checklist (PCL-M). Statistically significant differences in PSQI scores and PCL-M scores were noted post treatment in the intervention group as compared to the wait list control group ($p = .04$, $p = .05$).[5] This study was limited by: 1) an extremely small sample size ($n = 5$), 2) lack of sham group and, 3) lack of monitoring hypnotic medications or conventional care during the study period.

The results of these studies and the current study (USU Grant Number HT9404-12-1-TS15, USU Project Number N12-P15) provides some preliminary data that favors the use of acupuncture for veterans with PTSD and insomnia. However, these studies have similar limitations and should be addressed in future studies. Future studies which include AA as in intervention for sleep should incorporate larger sample sizes, sham AA, randomized control trials, and monitoring of hypnotic medications & conventional care during the study period.

Effect of problems or obstacles on the results:

One of the most challenging aspects of this study was the complex clinical nature of veterans with PTSD. In addition to sleep disturbances, subjects in this study were also affected by numerous other co-morbid conditions including: anxiety, depression, alcohol dependence, and chronic pain. This complex clinical picture presented numerous challenges to adequately measure the effect of the AA on sleep quality and sleep disturbance because many of these co-morbid conditions likely have an effect on sleep quality. Although it was beyond the scope of the present study to measure symptoms of other co-morbid conditions, the co-morbid condition of chronic pain was captured from the demographic questionnaire. Seventy percent of subjects reported the presence of chronic pain (70%), and this may have been a confounding factor in this study. Previous investigations have supported the use of acupuncture for pain conditions (due to the release of endogenous endorphins),[6,7] therefore, the effect of the AA treatments in this study on subjective sleep quality may have been a result of improved pain relief.

Anther challenging aspect of conducting this study was the high attrition rate (33% overall, 20% AA group, 43% control group). The high attrition rate was largely due to the high

number of adverse events during the study. These adverse events resulted in a large number of subjects withdrawing from the residential PTSD program, and therefore withdrawing from the study. Although these adverse events were deemed to be unrelated to the study protocol or receiving acupuncture, these events frequently occur in this population. This presented challenges to retain subjects in the study, reduced the amount of data available to analyze, and is a source of potential bias within the sample.

Adherence by subjects to record sleep measures in the sleep diary and wearing the actigraph was challenging. Subjects were more compliant with wearing the actigraphs than recording sleep measures in the sleep diary as displayed in Table 2. This challenge resulted in missing actigraphy, sleep diary data, and compromised the data analysis. Challenges with adherence in this study may have been a result of the numerous requirements of the PTSD residential treatment program (i.e. written assignments) in addition to complying with the requirements of participating in the study. The use of incentives for populations with insomnia has been recommended by sleep experts [personal communication with Dr. Jennifer Martin 10/23/13] and may increase subject adherence to data collection methods.

The use of sleep medications was not controlled during this study. Controlling for sleep medications would have allowed more transparency in evaluating the acupuncture intervention. However, conducting this study would not have been possible since the majority of veterans with PTSD at the study site used sleep medications (an amendment was requested by the PI and approved at the NMCSD IRB, USD IRB, and USUHS IRB). The investigators of this study decided to examine sleep medication usage over time, which revealed no statistically significant change in sleep medication usage at week five as measured by the PSQI (Table 9). Limiting medication changes in this study was believed to self-select higher functioning veterans with PTSD and limit the ability to conduct a study with this population who could benefit from non-pharmacologic options to improve sleep.

An additional unexpected challenge to conduct this research was that the PCL and PHQ data collected from the clinic was placed in the subjects permanent medical record. This information can be examined for medical evaluation upon separation or retirement from active duty service. Therefore, there is a possibility that a conflict of interest was present for PCL and PHQ data. Future studies with this population may also benefit from a certification of confidentiality when administering instruments, which measure depression and PTSD symptoms.

Limitations:

Limitations of this study include: 1) a power analysis was not conducted prior to starting this study because the primary aim of this study was to evaluate feasibility and acceptability of AA interventions to veterans with PTSD, 2) the exclusion of female subjects in this study was primarily due to the low admission rate of female veterans with combat related PTSD at the study site. Therefore, few, if any, female subjects would be in the study. The findings of this study should be interpreted with caution and may not be generalizable to female veterans with PTSD and sleep disturbance, 3) a sham acupuncture group was not used in this study because of the feasibility design of the study. Sham acupuncture remains controversial and is believed to have an effect and 4) the use of hypnotic sleep medications was not controlled.

Conclusion:

Aim#1: Compare acupuncture acceptability between groups utilizing a Likert 1-5 scale, and examine the feasibility of an AA intervention study utilizing a consort diagram to track subject disposition throughout the study period.

The results of this feasibility study demonstrate the acceptability of using an AA treatment for insomnia among subjects in this investigation was high, as subjects readily volunteered to participate in this study and receive AA treatments. Further, data from a likert type question demonstrated subjects who received the AA treatment largely viewed it as an acceptable treatment for sleep disturbance at noted in Table 1.

Acceptability of the AA treatment was also demonstrated by the subjective comments made by subjects who described a variety of benefits of receiving the AA treatments. Since AA treatments were well received by veterans with PTSD and these treatments are relatively low risk, future studies would benefit from further exploring these benefits when conducting AA studies among veterans with PTSD.

Feasibility of the overall study design was examined with a consort diagram (figure 1). Although the study design of this investigation was feasible, the complex clinical nature of the subjects, high attrition rate, and adherence to the data collection instruments were challenging aspects of conducting this investigation. Therefore, the investigators of this study believe this study demonstrated a reasonable enrollment and retention rate for the implementation of the study design among veterans with PTSD receiving treatment in a residential treatment program. Future studies with this population would benefit from careful consideration of items to minimize subject burden: brief data collection instruments, brief interventions, etc. Further, the use of incentives may improve adherence to data collection methods in this population, thereby improving data available to analyze.

Aim #2: Compare objective (actigraphy data) and subjective sleep measures (PSQI and sleep diaries) at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Our findings on the use of an AA insomnia regimen demonstrated a three week intervention did not have a significant effect on the sleep measures we examined. However, it should be noted this was a pilot study and was not powered to examine AA effects on sleep outcomes. The majority of sleep measures by actigraphy and CSD actually worsened during the study period and this is believed to be related to the concurrent cognitive processing therapy subjects were participating in. Larger, adequately powered studies will be needed to evaluate AA effects on sleep outcomes in patients with PTSD. Effect sizes identified in this study could be used to power future studies.

The significant difference between the AA intervention group and control group for the PSQI components sleep quality and daytime dysfunction were an interesting finding of this study. Since the PSQI was administered to subjects at the closest time interval to the administration of AA intervention, there may be a short-term effect on sleep, but was not captured by other study instruments. Specifically, since actigraphy and sleep diary data was recorded the week after the AA intervention, there may have been short-term improvements in sleep not captured by the timing of data collection. Future investigations may benefit from collecting sleep measurement data closer to the timing of the AA interventions.

Another consideration of timing may be to employ the AA intervention later in the residential PTSD program. This may demonstrate greater improvements in sleep at a time when PTSD symptoms and sleep disturbances tend to return to baseline values. Alternatively, a longer AA intervention during the entire course of treatment may have been beneficial.

Aim #3: Compare PTSD symptoms and depressive symptoms at baseline and at five weeks in OEF/OIF veterans with PTSD who receive auricular acupuncture in conjunction with standard PTSD therapy or standard PTSD therapy alone.

Aim#4: Compare PTSD symptoms (PCL-M) and depressive symptoms (PHQ) weekly during the study period (baseline, week three, week five) between OEF/OIF veterans who receive auricular acupuncture as compared to those that receive standard PTSD therapy alone.

Conclusion of Aim #3 & Aim #4:

The results of PTSD symptoms (PCL-M) and depression symptoms (PHQ) measured both at baseline and five weeks and over time during the study period were not significantly different between groups. This finding may be a result of an unpowered sample or that AA does not affect PTSD and depression symptoms. It is important to note that the population of veterans treated at the residential PTSD program have some of the most severe cases of PTSD on active duty and the majority of veterans planned to leave active duty service. Therefore, a potential conflict of interest may have been present. Since PCL and PHQ scores are part of the permanent medical record of veterans and medical records are reviewed as part of the disability process future studies would benefit from obtaining a certificate of confidentiality for study instruments.

Significance of Study or Project Results to Military Nursing

This study provided preliminary data that AA treatments are highly acceptable to veterans with PTSD and improved subjective sleep quality in the group that received AA treatments. These findings are particularly important to military nursing because a military nurse administered the AA treatments in this study. Although the study design planned for a medical acupuncturist administer the AA treatments during the study, the medical acupuncturist transferred to another clinic, and was unable to perform the AA treatments. The PI assumed the delivery of the treatments per the backup plan described in the study protocol. The PI had performed in excess of 200 AA treatments prior to the study commencing.

Although the acceptability of receiving AA treatments performed by a nurse was not a specific aim of the study, the high acceptability of AA treatments and improvements in subjective sleep quality suggest patients that receive AA administered by nurses have similar outcomes to other AA providers.

This finding is critically important, as military nurses have recently been allowed to receive training and practice AA under a defined scope of practice. During the study period (March 2013), the Bureau of Medicine and Surgery Instruction for acupuncture training, privileging, and clinical practice established a 'tiered approach' to training military providers to perform acupuncture (BUMED Instruction 6320.100). This instruction not only allows military nurses to expand their clinical practice, but also will allow a greater number of veterans access to AA treatments. Military nurses are in a unique position to provide AA treatments as they provide care to veterans throughout the continuum of care: from forward deployed combat settings, enroute care, inpatient settings, and during rehabilitation. This change in practice and policy will allow military nurses to take a leading role in providing AA treatments to veterans entrusted to our care.

While the current study provided some preliminary data on acceptability of AA treatments and subjective sleep quality, future studies with more rigorous research methods are clearly needed. Based on the findings of this study, future studies should include powered samples, the inclusion of female subjects, sham acupuncture devices, tracking of sleep medications, and certificates of confidentiality.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

None to date

Mentor Evaluation

Mentorship Meetings-Frequency of Contact Dr. Cynthia Connelly to CDR Heather King, NC, USN	Date:	Action taken:
Discussion- data collection complete discussed scoring of actigraphy and sleep diary data.	9/18/13	Scored actigraphy and sleep diary data.
Discussion of data review with sleep expert.	10/23/13	Met with Dr. Jennifer Martin review actigraphy and sleep diary scoring.
Discussed data analysis.	10/30/13	Worked on data analysis.
Discussed data analysis.	11/4/13	Worked on data analysis.
Discussed data analysis.	11/11/13	Worked on data analysis.
Discussed final defense presentation.	11/14/13	Reviewed final defense presentation/edits.
Discussed /reviewed final dissertation documents.	11/20/13	Reviewed final dissertation documents/edits.
Final Dissertation Defense.	12/2/13	Successful defense of dissertation.
Review of prepared manuscript for publication.	3/1/2014	Sent documents electronically for review.
Send final USD IRB documents for review and closure of study	7/1/14	Sent documents electronically for review.

CDR Heather King successfully defended her dissertation research 12/2/13. She received her PhD in Nursing from the University of San Diego's School of Nursing 1/30/14. She completed all requirements for the USD IRB, NMCSD IRB, and TSNRP reports for her dissertation research. I strongly recommend that CDR King continue with her program of research and conduct a larger study investigating auricular acupuncture in veterans with post traumatic stress disorder.

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Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications	None	
Publications in Press	Title: Auricular Acupuncture for Sleep Disturbance among Veterans with Post Traumatic Stress Disorder: A Feasibility Study Authors: King, H., Sargent, P., Hickey, A., Spence, D., Elesh, R., Connelly, C. Journal: Military Medicine: submitted 8/11/14, currently under review	7/25/14 BUMED PAO
Published	None	
Podium Presentations	Authors: King, H., Sargent, P., Hickey, A., Spence, D., Elesh, R., Connelly, C. Title: Auricular Acupuncture for Sleep Disturbance in Veterans with Post Traumatic Stress Disorder Conference: American Psychiatric Association Annual Meeting Location: New York, NY Date of Presentation: 04 May 2014 Sponsoring Agency: TSNRP	9/9/14: NMCSD PAO

	Authors: King, H., Sargent, P., Hickey, A., Spence, D., Elesh, R., Connelly, C. Title: Auricular Acupuncture for Sleep Disturbance in Veterans with Post Traumatic Stress Disorder Conference: Tri-Service Nursing Research Dissemination Conference Location: San Antonio, TX Date of Presentation: 16 Sept. 2014 Sponsoring Agency: TSNRP	9/8/14: NMCSD PAO
Poster Presentations	Authors: King, H., Sargent, P., Hickey, A., Spence, D., Elesh, R., Connelly, C. Title of Poster: Auricular Acupuncture for Sleep Disturbance in Veterans with Post Traumatic Stress Disorder Conference: Academic Research Competition Location: San Diego, CA Date of Presentation: 4/25/14 Sponsor: Naval Medical Center San Diego	4/8/14: NMCSD PAO
	Authors: King, H., Sargent, P., Hickey, A., Spence, D., Elesh, R., Connelly, C. Title of Poster: Transforming Veteran Care: Responses to an Acupuncture Interventions among Veterans with Post Traumatic Stress Disorder Conference: Western Institute of Nursing Research Sponsor: none	6/3/14 BUMED PAO

Media Reports	Title: Sleep solutions: What docs are doing to help troops get some shut-eye (PI CDR King quoted in article from podium presentation at American Psychiatric Association Meeting 5/4/14). Type of Media: Internet news article, Military Times Date of Report: 12 May 2014	
Other		

Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	None
Issued a Patent	None
Developed a cell line	None
Developed a tissue or serum repository	None
Developed a data registry	None

Recruitment and Retention Table

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	30
Subjects Available	60
Subjects Contacted or Reached by Approved Recruitment Method	60
Subjects Screened	30
Subjects Ineligible	1
Subjects Refused	0
Human Subjects Consented	30
Subjects Who Withdrew	10
Subjects Who Completed Study	20
Subjects With Complete Data	11
Subjects with Incomplete Data	9

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	30
Subjects Available	60
Subjects Contacted or Reached by Approved Recruitment Method	60
Subjects Screened	30
Subjects Ineligible	1
Subjects Refused	0
Human Subjects Consented	30
Subjects Intervention Group / Control or Sham Group	15
Intervention Group / Control or Sham Group Subjects Who Withdrew	3
Intervention Group / Control or Sham Group Subjects Who Completed Study	12
Intervention Group / Control or Sham Group Subjects With Complete Data	10
Intervention Group / Control or Sham Group Subjects With Incomplete Data	2

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	30
Subjects Available	60
Subjects Contacted or Reached by Approved Recruitment Method	60
Subjects Screened	30
Subjects Ineligible	1
Subjects Refused	0
Human Subjects Consented	30
Subjects Control Group	14
Control Group/ Subjects Who Withdrew	6
Control Group Subjects Who Completed Study	8
Control Group Subjects With Complete Data	1
Control Group Subjects With Incomplete Data*	7

*Complete data for all subjects (intervention and control group) for PSQI data, PHQ data, PCL-M data. Actigraphy and sleep diary data missing as noted in Tables 4, 5, & 7.

Recruitment and Retention Aspect	Number
Medical or Data Registry Records Available	30
Medical or Data Registry Records Screened	0
Subjects Ineligible	1
Subjects With Complete Data	11
Subjects with Incomplete Data	9

Recruitment and Retention Aspect	Number
Animals Projected in Grant Application	0
Animals Purchased	0
Model Development Animals	0
Research Animals	0
Animals With Complete Data	0
Animals with Incomplete Data	0

Recruitment and Retention Aspect	Number
Animals Projected in Grant Application	0
Animals Purchased	0
Model Development Animals	0
Animals Intervention Group / Control or Sham Group	0
Intervention Group / Control or Sham Group Animals With Complete Data	0
Intervention Group / Control or Sham Group Animals With Incomplete Data	0

Recruitment and Retention Aspect	Number
Animals Projected in Grant Application	0
Animals Purchased	0
Model Development Animals	0
Animals Intervention Group 1 / Intervention Group 2 / Control or Sham Group	0
Intervention Group 1 / Intervention Group 2 / Control or Sham Group Animals With Complete Data	0
Intervention Group 1 / Intervention Group 2 / Control or Sham Group Animals With Incomplete Data	0

Demographic Characteristics of the Sample

Table 12. Demographic Characteristics

Characteristic	
Age (yrs.), μ ± SD	33.1 ± 7.2
Years of Service, μ ± SD	12.5 ± 1.6
Times deployed, μ ± SD	3.8 ± 2.2
Women, n (%)	0(0)
Men, n (%)	20(100)
Race	
White, n (%)	9(45)
Black, n (%)	1(5)
Hispanic or Latino, n (%)	7(35)
Native Hawaiian or other Pacific Islander, n (%)	2(10)
Asian, n (%)	1(5)
Other, n (%)	0(0)
Marital Status	
Single/Divorced, n (%)	7(35)
Married, n (%)	13(65)
Education Level	
High School, n (%)	10(50)
Some college, no degree, n (%)	8(40)
Bachelor's Degree, n (%)	1(12.5)
Master's Degree, n (%)	1(12.5)
Military Service or Civilian	
Air Force, n (%)	0(0)
Army, n (%)	2(10)
Marine, n (%)	10(50)
Navy, n (%)	8(40)
Civilian, n (%)	0(0)

Table 12. Demographic Characteristics (cont.)

Characteristic (cont.)	
Service Component	20(100)
Active Duty, n (%)	0(0)
Reserve, n (%)	0(0)
National Guard, n (%)	0(0)
Retired Military, n (%)	0(0)
Prior Military, not Retired n (%)	0(0)
Military Dependent, n (%)	0(0)
Civilian, n (%)	0(0)
Enlisted & Officer Personnel	18(90)
Enlisted, n (%)	2(10)
Officer, n (%)	
Presence of Chronic Pain	
Yes, n (%)	21(70)
No, n (%)	9(30)
Clinical Characteristics	
Duration of PTSD, μ ± SD	5.4 ± 5.1
Duration of PTSD Treatment, μ ± SD	2.4 ± 3.1
Duration of Sleep Problems, μ ± SD	4.8 ± 3.5

Final Budget Report

Signed Final Budget.pdf

Additional Funds Modification:
3/18/13: Submitted TSNRP Grant Amendment Request Form to request additional funds of $1660.24 to cover an unanticipated CA tax use charge on research equipment (actigraphs, SPSS Software, acupuncture needles) and supply items.

5/1/13 Received notification that $1661.00 additional funds authorized by TSNRP to cover unanticipated costs of California tax use charge on supplies. New total grant award $26,305.00.

9/7/14: Total award amount was $26,305.00 and total expenditures were $24,823.55. This resulted in a variance of $1,481.45 not spent during the study period. This was a result of the laptop computer costing less than expected ($1286.10), the administrative costs less than expected (65.82), the copy expenses costing less than expected ($22.40), and the travel expenses costing less than expected ($739.66-conference waived registration fees for speakers).